Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
June 20, 2017

Board Members:

Present:

Zail Berry, MD	Jocelyn VanOpdorp, PharmD	Louise Rosales, NP
Renee Mosier, PharmD	Clayton English, PharmD	Bill Breen, RPh

Absent: Alisson Richards, MD, Patricia King, MD

Staff:

Laurie Brady, RPh, Change HealthCare	MaryBeth Bizzari, RPH, DVHA	Stacey Baker, DVHA
Steve Liles, PharmD, Change Healthcare	Carrie Germaine, DVHA	Scott Strenio, MD, DVHA
Jeff Barkin, MD, Change Healthcare	Jason Pope, DVHA	
	Michael Ouellette, RPh, Change HealthCare	

Guests:

Mario Carnovale, Novartis	Stew Hoover, UCB	Megan Walsh, Abbvie
Thomas Currier, Purdue	James Kokoszyna, Allergan	Franco Casagrande, Abbvie
Rod Francisco, Sunovian	Vincent Lawler, Genzyme	Jane Guo, Otsuka

1. Executive Session:

- An executive session was held from 6:00 p.m. until 6:40p.m.

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The May meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Updates: Mary Beth Bizzari, RPh, DVHA

- None at this time

4. Medical Director Update: Dr. Scott Strenio, DVHA

- No updates at this time.

5. Follow-up Items from Previous Meetings: Laurie Brady, RPh, Change Healthcare

- None at this time

6. RetroDUR/DUR: Laurie Brady, RPh, Change Healthcare

- **Data presentation: Twice Daily PPI Use**

Proton pump inhibitors are a class of medications that inhibit production of gastric acid by the parietal cells in the stomach. Developed over 20 years ago, they have been proven in clinical trials to be more effective than H2 antagonists in healing gastric ulcers, duodenal ulcers and esophagitis. Over time, PPIs have become first line therapy to treat these conditions, with indications of treatment that rarely exceed 12 weeks. While treatment of ulcers and esophagitis have guidelines for treatment duration, patients with GERD present a clinical challenge. American College of Gastroenterology guidelines do suggest that patients with GERD who are not free of symptoms after 8 weeks of maximal therapy be continued on intermittent or on demand therapy at the lowest effective dose, although the level of evidence is low.

Use of PPIs is widespread in VT, and many members are taking PPIs and H2 blockers concurrently. We examined the common diagnoses that would support the use of PPIs, including duodenal ulcer, GERD, esophagitis, helicobacter pylori ulcer, gastric ulcer, peptic ulcer, hypersecretory conditions, and esophageal ulcer. We also looked at how many members had a diagnosis code that would suggest a complication of long-term PPI use, including, hypomagnesemia, atrophic gastritis, diarrhea, C. difficile, pneumonia, and osteoporosis-related fractures.

For the calendar year 2016, 13,913 members had a prescription for a PPI, given once daily or less. 1,286 members had a prescription for 2 doses daily or greater. 205 members had a prescription for between 1-2 doses daily. It is important to understand that a member may have had more than one prescription written, so the member count may not be as high as the total of these 3 numbers. For example, a member could have started out on 1 dose/day but have that escalated to 2 doses/day if still symptomatic. That member would be double counted in that case. Looking at supporting diagnoses for members on ≥2 dosage units daily, 750 had a supporting diagnosis and 536 had no supporting diagnosis. Looking at members using one of the three preferred drugs at a dose of ≥2 dosage units daily, a total of 159 were also using an H2 blocker (Lansoprazole 25, Omeprazole 77, Pantoprazole 57). There are limited clinical reasons for a patient to be on both.

Nationally, there are many people on chronic PPI use. It is not clear that guidelines are being followed appropriately, or that ongoing interval evaluations are being done to assess the need for ongoing use.

Recommendation: Reassessment of members who have been on once or twice daily PPI's for 8 weeks to assess whether ongoing use is necessary and if so, whether the dose could be decreased to once daily. The AGA recently made a recommendation (April 2017) that PPI use should only be continued if symptoms recur after the medication has been discontinued, and restarted at the lowest possible dose.

Tighten up the criteria for use of the non-preferred PPIs since the AGA finds no evidence that one PPI is preferred over another.

Require a clinical PA for use of H2 blockers if the member is on PPI twice daily. The AGA recommendations (AGA guidelines for management of GERD, 2013) are that a nighttime H2 blocker can be added to a daytime PPI if objective evidence of nighttime reflux is documented, but caution that this may be associated with tachyphylaxis after a few weeks of use.

Consider requiring diagnosis of Barrett's esophagus or erosive esophagitis for long term continuation without requiring a trial off of medication. If the member is a on twice daily PPI, there could still be a requirement to decrease to once daily after 8 weeks. (AGA, 2013, Guidelines for management of GERD)

Board Decision: The Board decided that limits need to be placed on twice daily dosing for a diagnosis of GERD. There should be a 12-week limit on BID dosing when approving a prior authorization (PA). For continuation after 12 weeks, there must be a documented attempt to taper to once daily dosing of a PPI with adjunctive H2 Blockers (8-12 weeks is considered treatment failure). An educational letter should be sent to all pharmacies and providers. Follow up for Change Healthcare to collect data on utilization and cost of the non-preferred PPIs and present at the next meeting.

7. Clinical Update: Drug Reviews: Jeff Barkin, MD, Change Healthcare, and Laurie Brady RPh, Change Healthcare

Steve Liles, RPh, Change Healthcare presented Biosimilars and Interchangeable Biologicals

- Allows for approval of biologics through abbreviated pathway ("351K"). Biosimilarity to the reference product is based on data derived from analytical studies, animal studies (including assessment of toxicity), and clinical studies demonstrating safety, purity, and potency for at least one reference product indication. The FDA can extrapolate data to approve for all indications, which is what has occurred to date. This is not required, however, and the biosimilar does not have to be improved for all indications.

- Biosimilar designations: *Biosimilar*- Highly similar to reference product with no clinically meaningful differences in safety, effectiveness, purity, and potency. *Interchangeable*- Biosimilar that can be expected to produce the same clinical result as the reference product in any given patient, and the risk in terms of safety or diminished efficacy of switching between the biosimilar and the reference product is not greater than the risk of using the reference product. An interchangeable product may be substituted without intervention of the prescriber (per federal law).
- Biosimilars will have a brand name. It is unknown if interchangeable products will. Both will have the same core non-propriety name followed by a random four-letter suffix.
- CMS offered guidance to states. They indicated that biosimilars meet the definition of a single-source innovator drug and are subject to the higher minimum drug rebate.
- 50-60 biosimilars are in development. Half of those are in 3 anti-TNF drugs (adalimumab, etanercept, and infliximab), and 1/3 are in 4 oncology drugs (trastizumab, bevacizumab, rituximab, and cetuximab). Currently only two biosimilar products have been launched (Zarxio® and Inflectra®).

Abbreviated New Drug Reviews:

- None at this time.

Full New Drug Reviews:

b) Inflectra® [Infliximab-dyyb (biosimilar to Remicade)]

- Infliximab-dyyb, the active ingredient of Inflectra®, is a biosimilar to Remicade® (infliximab). It is a chimeric IgG1k monoclonal antibody specific for human tumor necrosis factor-alpha (TNF-alpha). Infliximab products neutralize the biological activity of TNF-alpha by binding with high affinity to TNF alpha and inhibit the binding of TNF alpha with its receptors. Inflectra® is indicated for:
  - Crohn's Disease (CD): To reduce signs/symptoms and induce/maintain clinical remission in adults with moderately to severely active CD who have had an inadequate response to conventional therapy AND to reduce the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adults with fistulizing CD.
  - Pediatrics Crohn's Disease: To reduce signs/symptoms and induce/maintain clinical remission in pediatric patients ≥6 years of age with moderately to severely active CD who have had an inadequate response to conventional therapy.
  - Ulcerative Colitis (UC): To reduce signs/symptoms, induce/maintain clinical remission and mucosal healing, as well as eliminating corticosteroid use in adults with moderately to severely active UC who had an inadequate response to conventional therapy.

- Rheumatoid Arthritis (RA): In combination with methotrexate to reduce signs/symptoms, inhibit the progression of structural damage, and improve physical function with moderately to severely active RA.
- Ankylosing Spondylitis (AS): To reduce signs/symptoms
- Psoriatic Arthritis (PA): To reduce signs/symptoms of active arthritis, inhibiting progression of structural damage, and improving physical function.
- Plaque Psoriasis (PP): Chronic severe PP for adults who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. Should only be administered to those who will be closely monitored and have regular follow-up visits with physician.

Inflectra® has a box warning regarding the increased risk of serious infections and malignancy with use. Serious infections may lead to hospitalization or death. Treatment should be discontinued if a serious infection or sepsis develops. The risks and benefits of treatment with Inflectra® should be carefully considered prior to starting therapy in patients with chronic or recurrent infection. In addition, the box warning also indicates lymphoma and other malignancies, some fatal, have been reported in children and adolescents treated with TNF blockers, including infliximab products. Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), have been reported in patients treated with TNF blockers, including infliximab products. There is no evidence at this time to support that Inflectra® is safer or more effective than the currently available, more cost effective medications, including Remicade®.

Public Comment: No public comment.

Recommendation:

Ankylosing Spondylitis: Injectables

- Add Inflectra® (infliximab-dyyb) biosimilar to Remicade to non-preferred.
  - Clinical criteria:
    - Add Inflectra to the Cimzia, Cosentyx, Remicade and Simponi criteria.
      - Additional criteria for Inflectra: the prescriber must provide a clinically valid reason why Remicade cannot be used.

Inflammatory Bowel Disease Injectables

- Add Inflectra® (infliximab-dyyb) biosimilar to Remicade to non-preferred.
- Add Stelara® (ustekinumab) to non-preferred.
  - Clinical criteria for Crohn's Disease:

- Add Inflectra and Stelara to the Humira, Remicade, Cimzia, Tysabri and Entyvio criteria.
- Add Inflectra® additional criteria: The prescriber must provide a clinically valid reason why Humira and Remicade cannot be used.
- Add Entyvio, Stelara additional criteria: Patient age > 18 years AND The patient has a documented side effect, allergy, treatment failure (including corticosteroid dependence despite therapy), or contraindication to BOTH Remicade and Humira Note: Initial IV dose for Stelara will be approved through the medical benefit. All subsequent subcutaneous doses may be approved through the pharmacy benefit with a quantity limit of 90mg every 8 weeks.

- Clinical Criteria for Ulcerative Collitis:
  - Add Inflectra: The patient has a diagnosis of Ulcerative Colitis and has had a documented side effect, allergy or treatment failure with at least 2 of the following 3 agents: aminosalicylates (e.g. sulfasalazine, mesalamine, etc), corticosteroids, or immunomodulators (e.g. azathioprine, 6-mercaptopurine, cyclosporine, etc.) AND the prescriber must provide a clinically valid reason why Humira and Remicade cannot be used

Psoriasis: Injectables

- Add Inflectra® (infliximab-dyyb) biosimilar to Remicade to non-preferred.
  - Clinical criteria:
    - Add Additional criteria for Inflectra®: The prescriber must provide a clinically valid reason why Humira®, Cosentyx®, and Remicade® cannot be used.

Rheumatoid, Juvenile, & Psoriatic Arthritis: Immunomodulators

- Add Inflectra® (infliximab-dyyb) biosimilar to Remicade to non-preferred.
  - Clinical criteria:
    - Add Inflectra® additional criteria: The prescriber must provide a clinically valid reason why both Humira and Enbrel cannot be used AND the patient must be unable to use Remicade.

Board Decision: The Board unanimously approved the above recommendation.

c) Spinraza® (nusinersen)

- Nusinersen, the active ingredient of Spinraza®, is a modified antisense oligonucleotide (ASO) to treat spinal muscular atrophy caused by mutations in chromosome 5q that lead to SMN protein deficiency. Per animal studies, Spinraza® was shown to increase exon 7 inclusion in SMN2 messenger ribonucleic acid (mRNA) transcripts and production of full-length SMN protein. It is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. Spinraza® is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures. The recommended dose is 12mg (5ml) per administration. Start with 4 loading doses, with the first 3 loading doses administered at 14-day intervals. The 4th loading dose should be administered 30 days after the 3rd dose. A maintenance dose should be administered once every 4 months thereafter. The safety and efficacy of Spinraza® were assessed in a double-blind, sham-procedure controlled trial that included symptomatic infantile-onset SMA patients ≤7 months of age at the time of first dose and diagnosed with SMA with symptom onset before 6 months of age. A planned interim efficacy analysis was conducted based on patients who died, withdrew, or completed at least 183 days of treatment. There were 82 patients included in the interim analysis. The results of the controlled trials in infantile-onset SMA patients were supported by open-label uncontrolled trials conducted in symptomatic SMA patients who ranged in age from 30 days to 15 years at the time of the first dose, and in presymptomatic patients who ranged in age from 8 days to 42 days at the time of the first dose. Some patients achieved milestones such as ability to sit unassisted, stand, or walk when they would otherwise not be expected to do so, maintained milestones at ages when they would have expected to be lost, and survived to ages unexpected considering the number of SMN2 gene copies of patients in the studies. The overall findings of the controlled trial in infantile-onset SMA and the open-label uncontrolled trials support the effectiveness of Spinraza® across the range of SMA patients, and seem to support the early start of treatment.

Recommendation:

- Add Spinraza® (nusinersen) injection to non-preferred.
    - Clinical criteria:
        - Spinraza: The diagnosis is spinal muscular atrophy (SMA) type 1, 2, or 3 (results of genetic testing must be submitted) AND The patient has at least 2 copies of the SMN2 gene AND The prescriber is a neurologist, pulmonologist, or other physician with expertise in treating SMA AND The need for invasive or noninvasive ventilation (if applicable) does not exceed more than 6 hours per 24 hour period AND Baseline motor ability has been established using one of the following exams: Hammersmith Infant Neurological Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSE), Upper Limb Module Test (non-

ambulatory), or Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) AND Prior to starting therapy, and prior to each dose, the following laboratory tests will be conducted: Platelet count, prothrombin time (PT), activated partial thromboplastin time (aPTT), and quantitative spot urine protein. **Note:** Initial approval will be granted for 4 loading doses (the first 3 loading doses should be administered at 14-day intervals; the 4th loading dose should be administered 30 days after the 3rd dose). Renewal may be granted for up to 12 months with a maximum of 3 doses approved per year (12mg (5ml) every 4 months). For therapy continuation, clinical documentation must be submitted documenting improvement or maintenance of motor ability OR slower progression of disease than would otherwise be expected.

Board Decision: The Board unanimously approved the above recommendation

d) Utibron® Neohaler (indacaterol & glycopyrrolate inhalation powder)

- Utibron® Neohaler is a combination product containing the active ingredients of indacaterol (a long-acting beta2-adrenergic agonist; LABA) and glycopyrrolate (a long-acting muscarinic antagonist (LAMA), often referred to as an anticholinergic). Indacaterol acts locally in the lung at the beta2 receptors in bronchial smooth muscle, working as a bronchodilator. In the airways, glycopyrrolate exerts its effect through inhibition of muscarinic receptor M3 at the smooth muscle, which leads to bronchodilation. Indicated to be used for a combination product for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Utibron® Neohaler is *NOT* indicated for the relief of acute bronchospasm or for the treatment of asthma. There is evidence that Utibron® Neohaler is more effective as compared to both its individual components when used as monotherapy (indacaterol and glycopyrrolate), and there is some evidence to support that Utibron® Neohaler may be more effective than some other available combination products. However, it is recommended that Utibron® Neohaler remain non-preferred and require prior authorization and be available to those who are unable to achieve therapeutic goals or who have failed on preferred, more cost effective alternatives.

Recommendation:

- Add Utibron™ Neohaler® to non-preferred with a quantity limit of 1 inhaler per 30 days.
    - Clinical criteria:

- Add Utibron Neohaler to the Anoro Ellipta and Bevespi Aerosphere criteria.

Public Comment: Amy Tomasello from Sunovion: Highlighted attributes of Utibron.

Board Decision: The Board unanimously approved the above recommendation.

8. Therapeutic Drug Classes – Periodic Review: Jeff Barkin, MD Change Healthcare and Laurie Brady, RPh, Change Healthcare

a) Angiotensin Modulators

- No new drugs.
- No significant changes.

Recommendation:

Ace Inhibitors and Combinations

- Add Captopril/ Hydrochlorothiazide to preferred.
- Remove Limitations: Captopril/HCTZ combination not covered. Agents may be prescribed separately from the clinical criteria.

Angiotensin Receptor Blockers (ARB's) and Combinations

- Move Benicar HCT to non-preferred.
- Add Olmesartan, Olmesartan/amlodipine and amlodipine/olmesartan/hydrochlorothiazide to non-preferred.
- Removed Teveten, Teveten HCT and Valturna from the PDL.
    - Clinical criteria:
        - Remove the Irbesartan, Losartan, Micardis, Valsartan, Irbesartan/HCTZ, Losartan/HCTZ, Micardis HCT, and Valsartan/HCTZ clinical criteria.
        - Update Atacand, Avapro, Benicar, Candasartan, Cozaar, Diovan, Edarbi, Eprosartan, Olmesartan, Telmisartan: patient has had a documented side effect, allergy, or treatment failure with a preferred Angiotensin Receptor Blocker (ARB) or ARB combination. AND If brand name product with generic available, the patient has had a documented intolerance with the generic product.
        - Update Avalide, Benicar HCT, Diovan HCT, Hyzaar, and Telmisartan HCT: patient has had a documented side effect, allergy, or treatment failure with a preferred Angiotensin Receptor Blocker (ARB) or ARB combination. AND If brand name product with generic available, the patient has had a documented intolerance with the generic product.

- Atacand HCT, candesartan/HCTZ, Hyzaar: patient has had a documented side effect, allergy, or treatment failure with a preferred ARB/Hydrochlorothiazide combination. AND If brand name product with generic available, the patient has had a documented intolerance with the generic product.
- Update Valsartan/amlodipine, Exforge: patient has had a documented side effect, allergy, or treatment failure to an angiotensin converting enzyme inhibitor (ACEI), an ACEI combination or any other angiotensin receptor blocker (ARB) or ARB combination AND if the request is for Exforge, the patient has had a documented intolerance with the generic product.
- Update Azor, Amlodipine/Telmisartan, Edarbyclor, Olmesartan/amlodipine, Olmestartan/amlodipine/HCTZ, Tribenzor, and Twynsta: The patient has had a documented side effect, allergy, or treatment failure to an angiotensin converting enzyme inhibitor (ACEI), an ACEI combination or any other angiotensin receptor blocker (ARB) or ARB combination. AND patient is unable to take the individual components separately. AND If the request is for a brand name product with generic available the patient has had a documented intolerance with the generic.
- Remove Valturna, Edarbyclor, Hyzaar, Teveten HCT, Benicar HCT, Irbesartan/HCTZ, Losartan/HCTZ, Micardis HCT, and Valsartan/HCTZ, Irbesartan, Losartan, Micardis and Valsartan and Tribenzor clinical criteria.
- Update Exforge HCT: patient has had a documented side effect, allergy, or treatment failure to an angiotensin converting enzyme inhibitor (ACEI), an ACEI combination or any other angiotensin receptor blocker (ARB) or ARB combination.

Renin Inhibitor

- Remove Amturnide, Tekamlo from the PDL.
- Clinical criteria:
  - Remove Amturnide, Tekalmo, Tekurna HCT clinical criteria.
  - Update Tekturna HCT: the patient must meet criteria as listed above for Tekturna and is unable to use the individual separate agents.
  - Update Tekturna: patient is NOT a diabetic who will continue on therapy with an ACEI or ARB AND patient has a diagnosis of hypertension. AND patient has had a documented side effect, allergy, or treatment failure with an angiotensin Receptor Blocker (ARB).

Board Decision: The Board unanimously approved the above recommendation.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

b) Beta Blockers

- No new drugs.
- No significant changes.

<u>Recommendation</u>:

Beta Blockers and Combinations

- Move Betaxolol, Innopran XL, and Nadolol to non-preferred.
- Remove Kerlone, Levatol, Sectral and Zebeta from the PDL.
- Move Propranolol ER to preferred.
    - Clinical criteria:
        - Add Hemangeol: indication for use is the treatment of proliferating infantile hemangioma**.**

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

Central Alpha Agonists

- Remove Nexiclon XR (suspension and tablets) and Tenex from the PDL.
- Move Catapres-TTS to preferred.
    - Clinical criteria:
        - Remove the Nexiclon XR tabs, Nexiclon Oral Suspension, and Catapres-TTS patch criteria.
        - Update Catapres tablets: Patient has a documented intolerance to the generic product.
        - Update Clonidine Patches (generic): patient has a documented intolerance to brand Catapres-TTS patches.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

c) Calcium Channel Blockers

- No new drugs.
- No significant changes.

<u>Recommendation</u>:

- Move Nicardipine, Nimodipine, and Diltiazem ER 12 hour capsules to non-preferred.
- Remove Nifediac CC, Dilt CD, and Nifedical XL from the PDL.
- Remove all of the CCB/Other Combination products from this therapeutic category. Add **Note:** Please refer to the Anti-Hypertensives: Angiotensin Receptor Blockers (ARBs) PDL category for ARB/CCB combination therapies.
    - Clinical criteria:
        - Remove the clinical criteria for Azor, Amlodipine/Telmisartan, Tribenzor, Twynsta, Amlodipine/atorvastatin, Caduet, Exforge, and Exforge HCT.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

d) Lipotropic- Other

- No new drugs.
- No significant changes.

<u>Recommendation</u>:

Bile Acid Sequestrants

- Move Welchol tablets, powder packets to preferred.
    - Clinical criteria:
        - Update clinical criteria for Questran, Questran Light, Colestid: The patient has had a documented intolerance to the preferred generic formulation.
        - Remove the clinical criteria for Welchol.

Fibric Acid Derivatives

- Move Fenofibric acid 45mg & 135mg delayed release cap to non-preferred.
- Remove quantity limit on Fibricor and Tricor.
    - Clinical criteria:
        - Remove Fenofibrate nanocrystallized, Fenofibric acid (45mg, 135mg) clinical criteria.
        - Update clinical criteria for Fenofibric acid to include all strengths.
        - Remove Note regarding fibrates: For patients receiving statin therapy, fenofibrate appears less likely to increase statin levels and thus may represent a safer choice than gemfibrozil for co-

administration in this group of patients - Am J Med 2004;116:408.

Homozygous Familial Hypercholesterolemia (HoFH) Agents

- Clinical criteria:
  - Update CRITERIA FOR APPROVAL: Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) AND Medication will be used as adjunct to a low-fat diet and other lipid-lowering treatments AND Patient does not have any of the following contraindications to therapy: ▪ Pregnancy (Juxtapid) ▪ Concomitant use with strong or moderate CYP3A4 inhibitors (Juxtapid) ▪ Moderate or severe hepatic impairment or active liver disease including unexplained persistent abnormal liver function tests (Juxtapid, Kynamro) AND Patient has trialed and had an inadequate response, intolerance or contraindication to BOTH atorvastatin and rosuvastatin.

Nicotinic Acid Derivatives

- No changes

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

PCSK9 Inhibitors

- Add quantity limit QL=2ml (75mg injection every 2 weeks or 300mg every month)/28 days. Max 28 days' supply to Praluent.
- Add quantity limit QL=2ml (2 injections)/28 days. Max 28 days' supply to Repatha® (evolocumab) Sureclick, prefilled syringe.
- Add Repatha® (evolocumab) Pushtronex™ with QL=3.5ml (One single-use infusor and prefilled cartridge)/28 days. Max 28 days' supply to non-preferred.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

e) Lipotrpic- Statins

- No new drugs.
- No significant changes.

Recommendation:

- Add Altoprev, Fluvastatin, Fluvastatin ER, Lescol® XL, Lipitor, Livalo, Mevacor, Pravachol, Zocor to non-preferred with **Note:** All non-preferred agents have a quantity limit of 1 tablet/day except fluvastatin IR which has a quantity limit of 2 tablets/day.
- Add Atorvastatin, Crestor, Lovastatin, Pravastatin, Rosuvastatin, Simvastatin to preferred with **Note:** All preferred agents have a quantity limit of 1 tablet/day.
    - Clinical criteria:
        - Non-preferred agents (except as noted below): The patient must have a documented side effect, allergy, or treatment failure to 3 preferred statins. If the product has an AB rated generic, one trial must be the generic formulation.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

Miscellaneous/Combos

- Remove Simcor and Liptruzet from the PDL.
- Add Ezetimibe and Ezetimibe/simvastatin to non-preferred.
    - Clinical criteria:
        - Add Ezetimibe: patient must have a documented intolerance to the brand name product.
        - Update Amlodipine/atorvastatin, Caduet: The patient is unable to take as the individual separate agents AND for approval of Caduet, the patient must have also had a documented intolerance to the generic equivalent.
        - Update Vytorin, ezetimibe/simvastatin: The patient has had an inadequate response to atorvastatin or rosuvastatin AND If the request is for a dose of 10/80mg, the patient has been taking this dose for 12 or more months without evidence of muscle toxicity.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

f) Iron Chelating Agents

- No new drugs.
- No significant changes.

Recommendation:

- No changes.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

9. Newly Developed/Revised Criteria: Laurie Brady, RPh, Change Healthcare

- Cystic Fibrosis
  - Updated Kalydeco: The patient has a diagnosis of Cystic Fibrosis. AND Patient has one of the following mutations on at least one allele in the cystic fibrosis transmembrane conductance regulator gene (CFTR gene): A1067T, A455E, D110E, D110H, D1152H, D1270N, D579G, E193, KE56K, F1052V, F1074L, G551D, G1069R, G1244E, G1349D, G178R, G551S, K1060T, L206W, P67L, R1070Q, R1070W, R117C, R117H,R347H, R352Q, R74W, S945L, S977F, S1251N, S1255P, S549N, S549R (documentation provided). AND The patient is ≥2 years old. Note: Renewal of Prior Authorization will require documentation of member response.

    Public Comment: Letter from Cystic Fibrosis Foundation: Wrote to support the revisions of the criteria of Ivacaftor to expand coverage to all CF patients 2 years and older with qualifying mutation.

- Epinephrine Auto- Injectors
  - Move Epinephrine Inj 0.15mg and 0.3mg, Epipen®2-PAK Inj 0.3mg, and Epipen-Jr®2-PAK inj 0.15mg to non-preferred.
  - Add EPINEPHRINE INJ (compare to Epipen-Jr®) (authorized generic, Mylan labeler code 49502 is the only preferred form) 0.15mg to preferred.
  - Add EPINEPHRINE INJ (compare to Epipen®) (authorized generic, Mylan labeler code 49502 is the only preferred form) 0.3mg to preferred.
    - Clinical criteria
      - Remove Adrenaclick criteria.
      - Add criteria Epipen, Adrenaclick, non-authorized generics: The patient must have a documented intolerance to the authorized generic epinephrine.

- Interleukin (IK)- 1 Receptors Blockers
    - Update Ilaris: The diagnosis is Cryopyrin-Associated Periodic Syndrome (CAPS), Familial Cold Autoinflammatory Syndrome (FCAS), Familial Mediterranean Fever (FMF), Hyper-IgD periodic fever syndrome (HIDS), Muckle-Wells Syndrome (MWS), or Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) AND The patient is > 4 years old OR The diagnosis is systemic juvenile idiopathic arthritis (sJIA) with active systemic features and varying degrees of synovitis with continued disease activity after initial therapy (initial therapy defined as 1 month of anakinra (Kineret), 2 weeks of glucocorticoid monotherapy (oral or IV) or one month of NSAIDs). AND patient is > 2 years of age.

Board Decision: The Board unanimously approved the above recommendation.

10. General Announcements:
Selected FDA Safety Alerts

FDA Drug Safety Communication: FDA updates warnings for oral and injectable fluoroquinolone antibiotics due to disabling side effects
https://www.fda.gov/Drugs/DrugSafety/ucm511530.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Canagliflozin (Invokana, Invokamet): Drug Safety Communication - Increased Risk of Leg and Foot Amputations
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm558605.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA identifies no harmful effects to date with brain retention of gadolinium-based contrast agents for MRIs; review to continue
https://www.fda.gov/Drugs/DrugSafety/ucm559007.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

12. Adjourn: Meeting adjourned at 8:28 p.m.